

Appl. No. 10/520,236
Amdt. Dated October 31, 2006
Reply to Office Action of July 31, 2006

Attorney Docket No. 81844.0032
Customer No. 26021

REMARKS

This application has been carefully reviewed in light of the Office Action dated July 31, 2006. Claims 1-16 remain in this application. Claim 1 is the independent Claim. Claim 1 has been amended. Claim 2 has been canceled without prejudice. It is believed that no new matter is involved in the amendments or arguments presented herein. Reconsideration and entrance of the amendment in the application are respectfully requested.

Art-Based Rejections

Claims 1-4 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,833,644 (Zadno-Azizi) in view of U.S. Patent No. 5,667,521 (Keown); Claims 5-8 were rejected under § 103(a) over Zadno-Azizi in view of Keown and further in view of U.S. Patent No. 5,308,342 (Sepetka); Claims 9-12 were rejected under § 103(a) over Zadno-Azizi in view of Keown, and further in view of U.S. Patent No. 5,536,248 (Weaver); Claims 13-16 were rejected under § 103(a) over Zadno-Azizi in view of Keown and further in view of Sepetka.

The Keown Reference

Keown is directed to over the wire PTCA balloon catheters, and more particularly to a rapid exchange catheter with the guide wire lumen at the distal tip, wherein the exchange lumen is short.

Keown goes on to disclose that the Keown invention tends to minimize the likelihood of guidewire seizure during catheter withdrawal by both positioning the exchange component distal to the inflatable balloon and by using a short exchange lumen which keeps the guidewire relatively straight. A guidewire lumen of 0.75 cm can be used. Another factor which tends to minimize the likelihood of guidewire

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seizure in the present invention includes the low coefficient of friction in materials such as polyimide. (See, *Keown, Abstract*; col. 4, line 65; col. 5, lines 19-27)

The Sepetka et al. Reference

Sepetka is directed to a catheter composed of an outer coaxial tube of relatively high flexibility and three tandemly disposed inner coaxial tube segments that vary in stiffness. (See, *Sepetka, Abstract*)

The Weaver et al. Reference

Weaver is directed to a method of electrosurgically obtaining access to the biliary tree of a patient and visualizing a duct thereof using a catheter having at least a first lumen and a second lumen. (See, *Weaver, Abstract*)

The Zadno-Azizi et al. Reference

Zadno-Azizi et al. is directed to a multi-catheter emboli containment system in which a treatment chamber within a blood vessel is formed by at least two occlusion balloons on opposite sides of a stenotic lesion, thereby preventing emboli migration during the treatment procedure. It goes on to disclose a catheter 280 comprising an elongated shaft 282 with a lumen 284 for aspiration. At the distal end 288 of elongated shaft 282, a separate inner catheter lumen 286 is positioned adjacent the main aspiration lumen 284. This inner catheter or guidewire lumen 286 can be as short as 5 cm, but can extend 30 cm or larger in proximal direction. (See *Zadno-Azizi, Abstract*; col. 11, line 58 - col. 12, line 1; Fig. 14-15)

The Claims are Patentable Over the Cited References

The present application is generally directed to an aspiration catheter.

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As defined by amended independent Claim 1, an aspiration catheter includes a main shaft with an aspiration lumen disposed therein. The aspiration lumen extends from the proximal end to the distal end of the main shaft. A guidewire shaft with a guidewire lumen disposed therein. The guidewire lumen follows a guidewire. The guidewire shaft is positioned at the distal end of the main shaft. A hub is located at the proximal end of the main shaft. The tip of the main shaft is obliquely cut. The distal end of the guidewire shaft is positioned at the distal end of the main shaft or it protrudes from the distal end of the main shaft in the distal direction. The relationships $2 \text{ mm} \leq L1 \leq 10 \text{ mm}$, $0.5 \leq L2/L1$ and $L2 - L1 \leq 5 \text{ mm}$ are satisfied, where $L1$ is the length of the obliquely cut portion of the main shaft in the longitudinal direction of the catheter, and $L2$ is the length from the proximal end of the guidewire shaft to the distal end of the main shaft.

The applied references, either alone or combined, do not disclose or suggest the above features of the present application as defined by amended independent Claim 1. In particular the applied references do not disclose or suggest, "the relationships $2 \text{ mm} \leq L1 \leq 10 \text{ mm}$, $0.5 \leq L2/L1$ and $L2 - L1 \leq 5 \text{ mm}$ are satisfied", as required by amended independent Claim 1.

As asserted by the Office Action Zadno-Azizi, in col. 10, lines 56-58, discloses a guide wire lumen with a length $L2$ ranging between 50 mm – 300 mm. The Office Action on page 2 also asserts that Zadno-Azizi fails to teach or suggest that " $L2 - L1 \leq 5 \text{ mm}$ " as required by amended independent Claim 1, as such Zadno-Azizi remains silent regarding specific values of length $L1$ and how they may be chosen in relation to $L2$. Moreover, as claimed by amended independent Claim 1, $L1$ can be at most 10 mm and because $L2 - L1 \leq 5 \text{ mm}$ the maximum length of $L2$ is 15 mm, which is well below the 50 mm disclosed by Zadno-Azizi.

Thus Zadno-Azizi fails to disclose, teach, or suggest each and every element of amended independent Claim 1.

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The Office Action cites Keown as remedying the deficiencies of Zadno-Azizi. The Office Action states that Keown discloses a short guide wire lumen.

However, applicants respectfully submit that the Office Action fails to indicate where Keown specifically indicates the relationship " $L2 - L1 \leq 5 \text{ mm}$ " as required by amended independent Claim 1.

Moreover, as discussed above Keown discloses minimizing the likely hood of guide wire seizure by using a short exchange lumen in combination with positioning the exchange component distal to the inflatable balloon. Other than indicating that the guide wire lumen should be 0.75 cm, Keown fails to specifically quantify the parameters that make up a range of effective short guide wire lumen lengths and how an effective short guide wire lumen length is to be chosen. Even though a L2 value of 0.75 cm is less than 15 mm, Keown remains silent regarding the value of L1 and as such fails to disclose, teach or suggest any effect this value of L2 would have on the value of L1.

The Office Action has stated on page 3 that further optimization within prior art conditions through routine experimentation is well known. However, the Office Action has failed to show where Zadno-Azizi and Keown discloses, teaches or suggests any information regarding the selection of an optimal value for L1. The Office Action also fails to show where Zadno-Azizi and Keown quantify any relationship between the values of L1 and L2 as required by the present application.

Even assuming arguendo that it is obvious to optimize the length L2 based on Zadno-Azizi and Keown, there is no indication within Zadno-Azizi and Keown as to how this selection effects the selection of length L1.

Further still, as discussed in the response to the previous Office Action and shown in the Specification on page 9 lines 9-24 the relation between L1 and L2 is critical to the optimization of an aspiration catheter in accordance with the present

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invention. Additional evidence of the critical nature of this relationship is shown in Table 1 which shows how the tractability of a catheter is effected by varying values of L1 and L2. Neither Zadno-Azizi nor Keown disclose or suggest the importance of this relationship.

Keown fails to remedy the deficiencies of Zadno-Azizi for at least the reasons indicated above. As such Zadno-Azizi combined with Keown fails disclose, teach, or suggest "the relationships $2 \text{ mm} \leq L1 \leq 10 \text{ mm}$, $0.5 \leq L2/L1$ and $L2 - L1 \leq 5 \text{ mm}$ are satisfied" as required by amended independent Claim 1. The ancillary references Sepetka and Weaver, fail to remedy the above deficiencies of Zadno-Azizi and Keown.

Since the applied references fail to disclose, teach or suggest the above features recited in amended independent Claim 1, these references cannot be said to anticipate or render obvious the invention which is the subject matter of that claim.

Accordingly, amended independent Claim 1 is believed to be in condition for allowance and such allowance is respectfully requested.

The remaining claims depend either directly or indirectly from independent Claim 1 and recite additional features of the invention which are neither disclosed nor fairly suggested by the applied references and are therefore also believed to be in condition for allowance and such allowance is requested.

Conclusion

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los

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Angeles, California telephone number (310) 785-4721 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,
HOGAN & HARTSON L.L.P.

Date: October 31, 2006

By:



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